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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,934	04/07/2006	Satomi Miyata	MIYATA 6	5550

1444 7590 12/18/2008

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,934	MIYATA ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The prosecution of this application has been transferred from examiner Joseph S. Kudla to examiner Isis Ghali.

The receipt is acknowledged of applicants' amendment, IDS, and Terminal disclaimer, all filed 08/22/2008.

Claims 1-16 have been canceled.

Claims 17-19 are pending and included in the prosecution.

Terminal Disclaimer

1. The terminal disclaimer filed on 08/22/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application 10491,138 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The following rejection has been overcome by virtue of applicants' amendment and remarks:

The rejection of claims 17-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The following rejection has been discussed in details in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmott et al. (US Patent 4,983,382), in view of all Breton et al. (US Patent Application Publication 2002/0012684) and Japanese Publication 10-147514 and provided by Applicant.

Wilmott et al. teach a method of improving the appearance of the skin comprising administering ascorbic acid (Claim 1). Wilmott et al. teach "the essential role played by ascorbic acid in the hydroxylation of proline and lysine, hence the formation and maintenance of collagen has been investigated widely and is well understood" (column 3, lines 1-4).

Wilmott et al. does not teach a method for enhancing collagen with a fatty acid or that the fatty acid can be derived from royal jelly.

Breton et al. teach 10-hydroxy-2-decenoic acid compounds are well suited for stimulating epidermal renewal and combating extrinsic cutaneous aging (Abstract). Breton et al. teach extrinsic aging causes detrimental clinical changes, such as large wrinkles and the formation of flaccid and weathered skin, and histopathological changes, such as an excessive accumulation of elastic material in the upper dermis and the degeneration of the collagen fibers (page 1, column 2, paragraph 12). Breton et al. teach a method of combating extrinsic cutaneous aging with administering to an

individual subject and effective amount of at least one 10-hydroxy-2-decenoic acid compound (page 3, column 1, paragraph 39).

Japanese Publication 10-147514 teaches 10-hydroxy-2-decenoic acid is an active ingredient of royal jelly (Problem to be solved). The 10-hydroxy-2-decenoic acid compound can be between 0.001 and 10% (Solution).

It would have been obvious to one of ordinary skill in the art at the time of the invention that since Wilmott et al. teach a method of improving the formation and maintenance of collagen comprising administering ascorbic acid and Breton et al. teach a method of combating extrinsic cutaneous aging (i.e., through stimulating epidermal renewal and slowing the degeneration of the collagen fibers) comprising administering an effective amount of at least one 10-hydroxy-2-decenoic acid compound, that a method utilizing a pharmaceutical composition combining the two would similarly be useful in enhancing collagen production and would render claims 17 and 19 obvious. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose .... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

It would have been obvious to one of ordinary skill in the art at the time of the invention that in view of Japanese Publication 10-147514, 10-hydroxy-2-decenoic acid is able to be purified from royal jelly, thus rendering instant claim 18 obvious.

Response to Arguments

6. Applicant's arguments filed 08/22/2008 have been fully considered but they are not persuasive.

Applicants traverse this rejection by arguing that the claimed method is for enhancing collagen production comprising administering a composition comprising (i) L-ascorbic acid or a derivative or a mixture thereof, and (ii) a fatty acid in combination. Experiment 1, pages 18-21 of the specification and Figure 1 show that fatty acid, i.e., 10- hydroxydecenoic acid, (10-HDA), exhibits no collagen production enhancing effect. However, Experiment 3 at pages 23-24 of the specification and Figure 5 show that 10-HDA enhances collagen in a concentration dependent manner in the presence of L-ascorbic and/or a derivative thereof. That is, the collagen production enhancing effect of L-ascorbic acid and/or its derivatives is synergistically increased when a fatty acid such as 10-HDA is used in combination therewith. None of the cited references teaches such advantageous effects of the combination of L-ascorbic acid and/or its derivatives with a fatty acid in enhancing collagen production.

In response to these arguments, it is argued that the present method requires only one step of administering composition, and the step is recited by the references.

Additionally, the claimed composition is disclosed by the combined teaching of the references. Further, the claimed invention as a whole is taught by the combination of the references. Both references aimed at enhancing collagen formation. Wilmott desired to enhance collagen formation and maintenance by using ascorbic acid, and Breton desired to fight collagen degeneration by using 10-HDA. As a matter of fact, Breton teaches composition comprising 10-HDA and agent for combating free radicals and listed ascorbic acid and esters thereof as suitable free radical combating agent. 10-HDA is present in royal jelly as evident by JP '514. Therefore, the cited references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that enhance collagen production and prevent its degeneration. As stated in *In re Kerkhoven,* 205 USPQ 1069, 1072 (CCPA 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose". See also *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA1972); *In re Susi*, 58 CCPA 1074, 1079-80) 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). As the court explained in *In re Crockett,* the idea of combining the two compositions flows logically from their having been individually taught in the prior art.

Based on the disclosure by these references that ascorbic and its derivatives and 10-HDA are used in compositions to enhance collagen production and prevents its degradation, an artisan of ordinary skill would have a reasonable expectation that a

combination of the substances would also be useful in creating compositions to enhance collagen production.

Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Further, it has been held that: “When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious,” the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.”

In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative

steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

Finally, a conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

In the light of the foregoing discussion, the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention. The Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611